

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

TARO PHARMACEUTICALS NORTH  
AMERICA, INC., and  
TARO PHARMACEUTICALS U.S.A.,  
INC.,

Plaintiffs,

v.

SYNERX PHARMA, LLC,  
and DPT LABORATORIES, LTD.,

Defendants.

Civil Action No.  
09-03569-JLL-CCC

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**BRIEF OF DEFENDANTS IN SUPPORT OF MOTION FOR LEAVE TO FILE THE  
SECOND AMENDED ANSWER AND COUNTERCLAIMS OF SYNERX PHARMA LLC  
AND SECOND AMENDED ANSWER OF DPT LABORATORIES, LTD.**

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## **INTRODUCTION**

Defendants Synerx Pharma, LLC (“Synerx”) and DPT Laboratories, Ltd. (“DPT”) respectfully submit this brief in support of their Motion for Leave to File the Second Amended Answer and Counterclaims of Synerx Pharma, LLC and Second Amended Answer of DPT Laboratories, Ltd. (the “Second Amended Answer”) to assert additional invalidity defenses and counterclaims under 35 U.S.C. § 102 and § 112 against the patent-in-suit, U.S. Patent No. 7,560,445 (“the ‘445 patent”).

As explained below, this motion is timely under the Court’s May 17, 2010 Scheduling Order, the proposed amendment will not prejudice any party, and the amendment is not futile. Defendants therefore respectfully request that this Court grant leave to file the Second Amended Answer pursuant to Federal Rule of Civil Procedure 15(a).

## **BACKGROUND**

Taro owns the patent-in-suit, which is entitled “Process for Preparing Malathion for Pharmaceutical Use.” The patent claims a topical pharmaceutical composition of a pesticide called malathion, as well as a process for preparing the malathion composition. Malathion itself is a well-known pesticide, and has been used to treat head lice for almost forty years. In fact, Ovide® lotion, Taro’s malathion-based head lice treatment, first entered the U.S. market back in 1982. (*See* Compl. ¶ 15.)

In December of 2006—before Synerx knew that Taro was seeking to patent a malathion product<sup>1</sup>—Synerx submitted an Abbreviated New Drug Application (“ANDA”) to the FDA seeking approval to market a generic malathion lotion. The FDA approved Synerx’s ANDA in March of 2009, and Synerx joined with Karalex Pharma, LLC (“Karalex”) and DPT to bring a

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<sup>1</sup> Indeed, Synerx could not know, as Taro’s pending patent application was not made public until January of 2007, *after* Synerx had already submitted its ANDA.

generic malathion product to market. Shortly after Synerx launched its malathion product, however, the PTO issued the '445 patent to Taro on July 14, 2009. No additional batches of Synerx's malathion product have been made or sold by or for Synerx since July 14, 2009.

A week later, on July 20, 2009, Taro sued Synerx, DPT and Karalex,<sup>2</sup> alleging infringement and demanding a jury trial. (Compl. 4-5.) In response, Defendants noted that they had "not made, offered for sale, sold, distributed, imported or used" their generic malathion product since the '445 patent issued. (Defs.' Answer at 9.) Thereafter, at Taro's request, the Court authorized a period of limited, one-way discovery in which Synerx provided to Taro documents supporting Synerx's contention that although all activities had ceased, Synerx remained committed to marketing its generic malathion product. In light of the controversy, Synerx counterclaimed for a declaratory judgment of invalidity or non-infringement. (Defs.' First Am. Answer at 11.)

Subsequently, the Court ordered the parties to submit schedules, and Taro's proposed schedule was adopted by the Court on May 17, 2010. Pursuant to that Scheduling Order, Defendants served their invalidity and noninfringement contentions on July 19, 2010. In those contentions, Defendants detailed their arguments regarding the '445 patent's invalidity based not only on obviousness under 35 U.S.C. § 103, but based on anticipation (35 U.S.C. § 102), lack of enablement (35 U.S.C. § 112, ¶ 1), and indefiniteness (35 U.S.C. § 112, ¶ 2). In addition, Defendants provided a detailed claim chart in accordance with L. Pat. R. 3.3.

In light of these developments, Defendants now move to amend to formally assert affirmative defenses and counterclaims directed to the invalidity of the '445 patent based on anticipation, lack of enablement, and indefiniteness. As explained in more detail below, this

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<sup>2</sup> Karalex was dismissed from the case on June 28, 2010.

motion is timely under the Court's May 17, 2010 Scheduling Order, the amendment will not prejudice any party, and the amendment is not futile. Thus, Defendants believe their request for leave to file the Second Amended Answer pursuant to Federal Rule of Civil Procedure 15(a) should be granted.

### **DISCUSSION**

#### **I. TARO WILL NOT SUFFER ANY PREJUDICE AS A RESULT OF DEFENDANTS' AMENDMENTS**

Defendants have moved to amend pursuant to Fed. R. Civ. P. 15(a), a rule which "embodies a liberal approach to pleading." *Arthur v. Maersk, Inc.*, 434 F.3d 196, 202 (3d Cir. 2006). In the Third Circuit,<sup>3</sup> "[l]eave to amend must generally be granted unless equitable considerations render it otherwise unjust." *Id.* at 204.

Under the relevant Rule 15 standard, "prejudice to the non-moving party is the touchstone" in evaluating whether Defendants should be permitted to amend. *Eisai Co., Ltd. v. Taro Pharms. USA, Inc.*, 247 F.R.D. 445, 448 (D.N.J. 2007); *see Lorenz v. CSX Corp.*, 1 F.3d 1406, 1413–14 (3d Cir. 1993). This "prejudice" question is not asked in the abstract; instead, the Court must evaluate the specific hardship Taro alleges it would suffer should Defendants' amendments be allowed. *See Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267, 273 (3d Cir. 2001).

In particular, the Court should consider "whether allowing an amendment would result in additional discovery, cost, and preparation to defend against new facts or new theories." *Id.* Here, Taro has stated that it does not oppose Defendants' motion, providing evidence that this

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<sup>3</sup> Although the Federal Circuit will have jurisdiction over any appeal in this case because the action arises under the patent laws, the Federal Circuit follows the precedent of the applicable regional circuit in matters of law outside that court's area of exclusive jurisdiction. *See Voda v. Cordis Corp.*, 476 F.3d 887, 892 (Fed. Cir. 2007).

amendment will not place a significant burden on Taro in terms of discovery, cost, or preparation. Further, Taro has been on notice of Defendants' anticipation, enablement, and indefiniteness defenses since at least December of 2009, when Defendants filed their first amended Answer. (*See* Defs.' First Am. Answer at 9–14.) In that pleading, Synerx set forth a detailed factual basis supporting its belief as to the '445 patent's invalidity based on anticipation, indefiniteness, and enablement. The same is true of Defendants' invalidity and non-infringement contentions, which were served on Taro in July of 2010 and again outlined these defenses in detail. Thus, Defendants' proposed amendments do not constitute "new facts or new theories"; Taro has been aware of the facts underlying Defendants' claims for months.

## **II. NO SECONDARY REASON JUSTIFIES DENIAL OF LEAVE TO AMEND**

In the Third Circuit, "[i]n the absence of substantial or undue prejudice, denial instead must be based on bad faith or dilatory motives, truly undue or unexplained delay, repeated failures to cure the deficiency by amendments previously allowed, or futility of amendment." *Lorenz*, 1 F.3d at 1414. As described below, none of these factors call for denial of Defendants' motion to amend.

This Court's May 17, 2010 Scheduling Order expressly granted the parties until December 17, 2010 to seek leave to file amended pleadings. Defendants have filed their motion within the timeframe permitted by the Court, and there is no evidence of bad faith—indeed, Taro does not oppose the amendment. Nor are Defendants' proposed amendments futile. Futility is governed by the same standard of legal sufficiency that governs Rule 12(b)(6); thus, the Court "must accept as true all of the factual allegations in the [pleading] as well as the reasonable inferences that can be drawn from them." *MedPointe Healthcare Inc. v. Hi-Tech Pharmacal Co.*, 380 F. Supp. 2d 457, 462 (D.N.J. 2005) (quoting *Brown v. Philip Morris Inc.*, 250 F.3d 789, 796 (3d Cir. 2001)). Defendants' proposed defenses and counterclaims are based upon the same

detailed factual bases that Synerx outlined in the First Amended Answer and Counterclaims. If taken as true, those allegations—which are reiterated in the proposed Second Amended Answer—support a finding that the ‘445 patent is invalid for obviousness, anticipation, lack of enablement, and indefiniteness. Moreover, Defendants’ additional examples of invalidity—being made under 35 U.S.C. § 102 and § 112 rather than § 103—require analysis under a different legal framework than the example of invalidity in the earlier Answers.

### **CONCLUSION**

Because Taro will suffer no prejudice, because Defendants acted in good faith to bring this question to the Court in a timely fashion, and because Defendants’ amendments will not be futile, Defendants respectfully requests that the Court grant leave to file the Second Amended Answer.

December 10, 2010

Respectfully submitted,

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